IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY, LLC, and WARNER-LAMBERT EXPORT, LTD.,	:	
Plaintiffs,	:	
v.	:	Civil Action No. 03-209-JJF (Consolidated)
RANBAXY LABORATORIES LIMITED and RANBAXY PHARMACEUTICALS, INC.,	:	
Defendants.	:	

Rudolf E. Hutz, Esquire, Jeffrey B. Bove, Esquire, Collins J. Seitz, Jr., Esquire and Mary W. Bourke, Esquire of CONNOLY BOVE LODGE & HUTZ LLP, Wilmington, Delaware
Attorneys for Plaintiffs.

Steven J. Balick, Esquire and John G. Day, Esquire of ASHBY & GEDDES, Wilmington, Delaware.
Of Counsel: Darrell L. Olson, Esquire, John P. Giezentanner, Esquire, Douglas G. Muehlhauser, Esquire, William R. Zimmerman, Esquire, Payson LeMeilleur, Esquire, Sheila N. Swaroop, Esquire, Darryl H. Steensma, Esquire and Walter S. Wu, Esquire of KNOBBE, MARTENS, OLSON & BEAR, LLP, Irvine, California.
Jay R. Deshmukh, Esquire and George E. Heibel, Esquire of RANBAXY, INC., Princeton, New Jersey.
Attorneys for Defendants.

MEMORANDUM OPINION

December 16, 2005
Wilmington, Delaware

Farnan, District Judge.

This action was brought by Plaintiffs, Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, Warner-Lambert Company, LLC and Warner-Lambert Export, Ltd. (collectively, "Pfizer") against Defendants, Ranbaxy Laboratories Limited and Ranbaxy Pharmaceuticals Incorporated (collectively, "Ranbaxy") for infringement of U.S. Patent No. 4,681,893 (the "'893 patent") and U.S. Patent No. 5,273,995 (the "'995 patent"). The '893 and '995 patents pertain to an atorvastatin calcium pharmaceutical composition sold by Pfizer under the registered name Lipitor®. Lipitor® is prescribed by doctors for the treatment of elevated cholesterol and is the largest selling pharmaceutical in history. This lawsuit arises in connection with Abbreviated New Drug Application ("ANDA") No. 76-477 filed by Ranbaxy seeking to commercially manufacture, use and sell a drug product containing atorvastatin calcium as its active agent. Pfizer filed four Complaints against Ranbaxy alleging that Ranbaxy's proposed ANDA product infringes the '893 and '995 patents under 35 U.S.C. § 271(e)(2). These Complaints have been consolidated into this action. By its Complaints, Pfizer has asserted two patents against Ranbaxy, the '893 patent and the '995 patent. Specifically, Pfizer alleges infringement of claims 1-4, 8 and 9 of the '893 patent and claim 6 of the '995 patent.

In response to Pfizer's Complaints, Ranbaxy filed an Answer and several Counterclaims. Ranbaxy alleges that it does not infringe either the '893 or '995 patents. Ranbaxy also challenges the validity of the patent term extension granted by the PTO for the '893 patent. With regard to the '995 patent, Ranbaxy contends that the asserted claim of the '995 patent, claim 6, is invalid for double patenting, obviousness and anticipation. Ranbaxy also contends that the '995 patent is unenforceable as a result of inequitable conduct by Warner-Lambert Company before the PTO.

The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338, because this action arises under the patent laws of the United States. The Court also has subject matter jurisdiction over Ranbaxy's counterclaims pursuant to 28 U.S.C. §§ 1338, 2201 and 2202. The parties have submitted to the personal jurisdiction of the Court, and venue in this District is appropriate pursuant to 28 U.S.C. §§ 1391 and 1400.

The Court conducted a bench trial on the issues presented by the parties.[1] This Memorandum Opinion constitutes the Court's findings of fact and conclusions of law on the issues raised

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[1] The bench trial began on November 11, 2004 and was completed on December 13, 2004. Post-trial briefing was completed on April 4, 2005. In addition, two post-trial evidentiary motions (D.I. 314, 319) were filed by Pfizer, which will be addressed separately by the Court.

during trial.

BACKGROUND

I. The Parties

Pfizer Inc. is a Delaware corporation having a place of business in Morris Plains, New Jersey and corporate offices in New York City. Warner-Lambert Company was a Delaware corporation that became a wholly-owned subsidiary of Pfizer Inc. on June 19, 2000. Warner-Lambert Company was then converted into Warner-Lambert Company, LLC, a Delaware limited liability company. Warner-Lambert Export, Ltd. is a corporation formerly organized under the laws of Ireland with a registered office located in Dublin, Ireland. Pfizer Ireland Pharmaceuticals is a partnership between C.P. Pharmaceuticals International, C.V., a limited partnership under the laws of the Netherlands, and Pfizer Overseas Pharmaceuticals, a private limited company incorporated in Ireland. Pfizer Ireland Pharmaceuticals is a wholly-owned subsidiary of Pfizer Inc. with registered offices in Dublin, Ireland. Through Parke-Davis Pharmaceuticals Research, a division of Warner-Lambert Company, Pfizer holds an approved New Drug Application for the atorvastatin calcium pharmaceutical composition sold under the name Lipitor®.

Ranbaxy Pharmaceuticals Incorporated is a Delaware corporation with a place of business located in Princeton, New Jersey. Ranbaxy Laboratories Limited is a corporation of India

with corporate offices located in New Delhi, India. Ranbaxy Pharmaceuticals Incorporated is a wholly-owned subsidiary of Ranbaxy Laboratories Limited.

II. The Patents Generally

A. The '893 Patent

The '893 patent is entitled "Trans-6-[2-(3- OR 4-carboxamido-substituted pyrrol-1-yl)alkyl]-4-hydroxypyran-2-one inhibitors of cholesterol synthesis." The inventor of the '893 patent is Dr. Bruce D. Roth. Pfizer has identified to the Food and Drug Administration that the '893 patent covers the atorvastatin calcium composition sold by Pfizer since 1997 under the name Lipitor®. The '893 patent was to expire on May 30, 2006; however, the PTO granted an extension pursuant to 35 U.S.C. § 156, extending the expiration date of the '893 patent to September 24, 2009, excluding a six month pediatric extension.

B. The '995 Patent

The '995 patent is entitled "[R-(R*,R*)]-2-(4-fluorophenyl)-β, δ-dihydroxy-5-(1-methylethyl-3-phenyl-4-[(phenylamino) carbonyl]-1H-pyrrole-1-heptanoic acid, its lactone form and salts thereof." Dr. Bruce D. Roth is also the inventor of the '995 patent. The compound covered by the '995 patent is commonly referred to as atorvastatin calcium. The '995 patent expires on December 28, 2010.

DISCUSSION

I. Claim Construction Of The '893 And '995 Patents

A. The Legal Principles Of Claim Construction

Claim construction is a question of law. Markman v. Westview Instruments, Inc., 52 F.3d 967, 977-78 (Fed. Cir. 1995), aff'd, 517 U.S. 370, 388-90 (1996). When construing the claims of a patent, a court considers the literal language of the claim, the patent specification and the prosecution history. Markman, 52 F.3d at 979. In Phillips v. AWH Corp., 415 F.3d 1303, 1312-1317 (Fed. Cir. 2005), the Federal Circuit reaffirmed the claim construction principles set forth in Markman and reemphasized that the specification is the single best source for discerning the meaning of a claim.

A court may consider extrinsic evidence, including expert and inventor testimony, dictionaries, and learned treatises, in order to assist it in understanding the underlying technology, the meaning of terms to one skilled in the art and how the invention works. Phillips, 415 F.3d at 318-319; Markman, 52 F.3d at 979-80 (citations omitted). However, extrinsic evidence is considered less reliable and less useful in claim construction than the patent and its prosecution history. Phillips, 415 F.3d at 318-319 (discussing "flaws" inherent in extrinsic evidence and noting that extrinsic evidence "is unlikely to result in a reliable interpretation of a patent claim scope unless considered

in the context of intrinsic evidence").

In addition to these fundamental claim construction principles, a court should also interpret the language in a claim by applying the ordinary and accustomed meaning of the words in the claim. Envirotech Corp. v. Al George, Inc., 730 F.2d 753, 759 (Fed. Cir. 1984). If the patent inventor clearly supplies a different meaning; however, then the claim should be interpreted according to the meaning supplied by the inventor. Markman, 52 F.3d at 980 (noting that patentee is free to be his own lexicographer, but emphasizing that any special definitions given to words must be clearly set forth in the patent). If possible, claims should be construed to uphold validity. In re Yamamoto, 740 F.2d 1569, 1571 & n.* (Fed. Cir. 1984) (citations omitted).

B. Scientific Background/Terminology Needed For Claim Construction

The parties' claim construction disputes impact the field of stereochemistry, a subfield of chemistry. Stereochemistry is concerned with the three-dimensional structure of organic molecules in space. An isomer is one of several molecular entities that have the same atomic composition or molecular formula, but a different stereochemical formula, meaning the atoms are the same in number and type but different in their spatial arrangement. Stereoisomers are compounds that have the same atoms and the same connection pattern of atoms or groups of atoms, but are different in the way that those atoms or groups of

atoms are arranged in space. Enantiomers are stereoisomers that are non-superimposable mirror images of each other. Enantiomers have identical physical properties, including solubilities and melting points, with the exception of their interactions with chiral matter and plane-polarized light. A racemate, or racemic mixture, is an equal mixture of two enantiomers, such that it contains 50% of one enantiomer and 50% of its opposite enantiomer. Racemates and enantiomers are distinct compounds, and in general, have different physical properties such as solubility and melting points.

Optical activity is a compound's ability to rotate plane-polarized light. A pure enantiomer rotates plane-polarized light in only one direction to the maximal amount permitted by that molecule. An unequal mixture of two opposite enantiomers is optically active and the degree of optical rotation reflects the percentage of each enantiomer present in the mixture. In a racemate, which is an equal mixture of two opposite enantiomers, the compound is not optically active, because the optical rotations of the enantiomers cancel each other out.

Chemists name and describe racemates and enantiomers with certain symbols and designations. In a molecule containing one asymmetric center, one enantiomer is designated as the R-enantiomer and its opposite is the S-enantiomer. A racemate is designated as an "RS" structure, because it contains equal

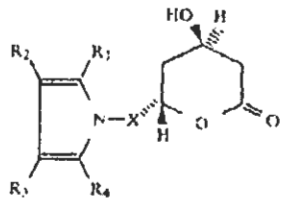
amounts of R and S enantiomers. A pure enantiomer is optically active because it rotates plane-polarized light either clockwise or counterclockwise. Chemists use a "+" symbol for the clockwise direction and a "-" symbol for the counterclockwise direction. A racemate is not optically active, and thus, chemists use the "±" to indicate a racemate.

The term "trans" is used to define the relationship of two groups to one another and indicates that two substituents are on opposite sides of a plane in a chemical structure. The term "cis" indicates that the two substituents are on the same side of the plane. Thus, the terms "cis" and "trans" describe relative stereochemistry.

Typically, when compounds are made synthetically in a lab, they are made as racemates. The process of isolating the enantiomers from a racemate is known as resolution.

C. The Claim Construction Of The '893 Patent

Pfizer asserts Claims 1-4, 8 and 9 of the '893 patent against Ranbaxy's ANDA product. Claim 1 is the only independent claim of the '893 patent and recites a compound of structural formula I drawn as:



I

This compound has a backbone of two rings joined by a bridge, designated as "X." The five-membered ring on the left contains a nitrogen atom designated as "N" and is a "pyrrole" ring. The six-membered ring on the right contains an oxygen atom ("O") and is a "pyran" or "lactone" ring. The left-hand ring has four possible substituents designated R_1 through R_4. Claim one of the patent designates the possible substituents for each of R_1, R_2, R_3, and R_4. The patent also designates the particular groups for X.

The parties' only claim construction dispute with respect to the '893 patent is what structural formula I represents. Ranbaxy contends that structural formula I represents only a genus of racemates. Pfizer agrees that claim 1 represents racemates, but contends that it is not limited to racemates. Pfizer contends that claim 1 also represents R-trans enantiomers, S-trans enantiomers and unequal mixtures of R-trans and S-trans enantiomers. The parties agree that structural formula I depicts an enantiomer; however, the parties also agree that this is not the meaning of structural formula I and that the meaning of structural formula I must be determined by reference to the context of the '893 patent.

After considering the claim language, the specification and the prosecution history of the '893 patent, the Court concludes that the '893 patent is not limited to racemates and embraces the two individual trans-form isomers, the R-trans and S-trans, as

well as their transform mixtures, including racemates. The Title, Abstract and Background sections of the '893 patent describe the invention as "trans" compounds. The Summary of the Invention then describes "certain trans" compounds and then defines the "broadest aspect of the present invention" as "compounds of structural formula I." DTX-13, col. 2, l. 2. In the Detailed Description section, the specification goes on to describe the "compounds of the present invention" as a "class of trans . . . " compounds. Id. at col. 3, l. 36-37. The patent expressly states:

> The compounds of structural formula I above possess two asymmetric carbon centers, one at the 4-hydroxy position of the pyran-2-one ring, and the other at the 6-position of the pyran 2-one ring where the alkylpyrrole group is attached. This asymmetry gives rise to four possible isomers, two of which are the R-cis- and S-cis-isomers and the other two of which are the R-trans- and S-trans-isomers. This invention contemplates only the trans-form of the compounds of formula I above.

Id. at col. 3, l. 45-54 (emphasis added). The Court understands this language to contemplate all trans-form compounds, including the individual R-trans isomer. In reaching this conclusion, the Court observes that the terms "racemate" or "racemic mixture" do not appear anywhere in the '893 patent, and there are no words of

limitation or chemical symbols used in claim 1 to restrict the meaning of "trans" or "trans-form" to the trans-racemate form.[2]

In contrast to claim 1, dependent claim 5 of the '893 patent uses the designation "Trans-(±)" to designate a racemic mixture. Ranbaxy contends that the use of this terminology should not be dispositive, because the patent identifies racemates in its examples without using the "±" designation. However, it is well-established that a claim is not limited by its examples or embodiments, unless the intrinsic evidence suggests an intent to so limit the claim. See e.g. Leibel Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 906 (Fed. Cir. 2004); Home Diagnostics, Inc. v. Lifescan, Inc., 381 F.3d 1352, 1357 (Fed. Cir. 2004) ("[T]he applicant's choice to describe only a single embodiment does not mean that the patent clearly and unambiguously disavowed other embodiments."). As discussed by the Court in more detail below, the express language of the patent indicates no intention to limit the claims to the compounds exemplified. Further, that the "±" designation was used in the express language of claim 5 and not in the language of the other claims suggests to the Court

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[2] The expert witnesses of both Pfizer and Ranbaxy agree that the term "trans" refers to two groups on opposite sides of the plane. The term does not denote any specific three dimensional configuration such as only R-trans, only S-trans, or only a 50/50 mixture or racemate. (Clive Tr. 1553:5-1554:9; Roush Tr. 884:7-23). Further, both experts also agree that each of the individual R-trans and S-trans isomers, along with all mixtures of those isomers are in the "trans-form." (Clive Tr. 1572:12-1574:15; Roush Tr. 233:23-234:5, 882:2-883:24).

that the inventor knew how to limit a claim to a racemate, but chose not to so restrict the other claims of the patent. Liebel-Flarsheim, 358 F.3d at 910 ("The presence of a dependent claim that adds a particular limitation raises a presumption that the limitation in question is not found in the independent claim.") (citations omitted); Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1119 (Fed. Cir. 2004) (recognizing that "when an applicant uses different terms in a claim it is permissible to infer that he intended his choice of different terms to reflect a differentiation in the meaning of those terms"). In the Court's view, a contrary conclusion would make the "±" term in claim 5 surplusage. Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp., 93 F.3d 1572, 1579 (Fed. Cir. 1996)

Ranbaxy contends that "by common convention, a racemate can be represented by depicting one of its constituent enantiomers." (D.I. 292 at 4) (emphasis added). Ranbaxy is correct that a depiction of an enantiomer can sometimes include or specify a racemate, but Ranbaxy has not demonstrated that, to one skilled in the art, such a depiction always or even usually specifies a racemate. Further, the fact that external sources may use an enantiomer to indicate a racemate does not overcome the intrinsic evidence of the '893 patent that the claimed invention is not limited to racemates. Phillips, 415 F.3d at 1319 (recognizing, to the extent extrinsic evidence is used in claim construction,

it must be considered in the context of the intrinsic evidence to be reliable).

Ranbaxy also seeks to limit the claimed invention to racemates because the reaction sequences and examples of the '893 patent are racemic. As the Court has concluded, however, the '893 patent is not limited to its examples and provides no indication that it should be so limited. For example, Table 1 of the patent reports results for test procedures used to determine the biological activity of examples of formula 1. However, the patent expressly identifies the Table 1 examples as "representative examples." Similarly, the '893 patent presents four working examples which also produce racemic mixtures; however, the patent states that these four examples "illustrate particular methods for preparing compounds in accordance with this invention. <u>These examples are illustrative and are not to be read as limiting the scope of the invention</u> . . ." DTX-13, col. 10, ll. 33-38 (emphasis added). Because the patent expressly evidences an intention that these examples be illustrative and the law disfavors limiting the patent based on its examples, the Court concludes that the reaction sequences and examples contained in the '893 patent do not limit the claimed invention to a racemic mixture or racemate.

Ranbaxy contends that if the Court accepts Pfizer's construction of the '893 patent, the patent is invalid for lack

of written description, because the patent does not disclose any methods for making enantiomers. In Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed. Cir. 1997), the Federal Circuit recognized that "in claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass." However, the Federal Circuit also acknowledged in Lilly its holding in Utter v. Hiraga, 845 F.2d 993, 998-999 (Fed. Cir. 1988), that "[a] specification may, within the meaning of § 112 ¶ 1, contain a written description of a broadly claimed invention without describing all species that claim encompasses." While the Federal Circuit declined to extend Utter in Lilly to claims involving genetic material, it did not abandon its holding for chemical materials noting that in the case of generic formulae, "[o]ne skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus." Lilly, 119 F.3d at 1568. In this case, the written description of the '893 patent is a generic formula which the patent specification expressly indicates includes all trans-enantiomers. Ranbaxy acknowledges that one skilled in the art would know how to resolve racemates into their constituent enantiomers, and therefore, the Court concludes that the generic formula description contained in the

'893 patent is sufficient to satisfy the written description requirement, regardless of whether the specific isomeric compounds are individually described in the patent.

Ranbaxy also contends that Warner-Lambert's representations during the prosecution of foreign counterparts to the '893 patent demonstrate that the '893 patent is limited to racemates. During the prosecution of the foreign counterparts to the '893 patent in Denmark and Europe, Warner-Lambert represented that the term "trans-" referred to "trans(±)." However, the Federal Circuit has recognized that "'the varying legal and procedural requirements for obtaining patent protection in foreign countries might render consideration of certain types of representations inappropriate' for consideration in a claim construction analysis of a United States counterpart." TI Group Auto. Sys. (N. Am.), Inc. v. VDO N. Am., L.L.C., 375 F.3d 1126, 1136 (Fed. Cir. 2004) (citations omitted). In the circumstances presented here, the Court finds that Warner-Lambert amended the Danish claims to limit them to racemates in response to the legal and procedural requirements specified by Danish law. Specifically, the Danish examiner found that under Danish law the scope of the claims was "too comprehensive." DTX 241 at P0279442. With respect to the European counterpart, Warner-Lambert made no actual amendments to the claims or specifications, but offered the "trans(±)" designation in response to the examiner's concerns that the

chemical nomenclature used in the patents was insufficiently articulated under European laws. The United States PTO raised no such concerns during the prosecution of the '893 patent, and Ranbaxy has not demonstrated to the Court any similarities between the foreign laws and the laws of the United States that would lead the Court to conclude that these changes and/or interpretations were not made in response to the unique aspects of the respective foreign laws under which patentability of the '893 counterparts was sought. Accordingly, the Court is not persuaded that Warner-Lambert's statements during the prosecution of foreign counterparts of the '893 patent are relevant to the Court's construction of the '893 patent issued in the United States.

In a similar vein, Ranbaxy contends that Pfizer is precluded from pursuing its proposed claim construction of the '893 patent based on statements made by Warner-Lambert during the prosecution of the '995 patent. However, the Federal Circuit has repeatedly held that arguments from a later, unrelated patent prosecution cannot be used to interpret and/or limit an earlier, unrelated and already issued patent.[3] Integra Lifesciences 1, Ltd. v. Merck KGaA, 331 F.3d 860, 868 (Fed. Cir. 2003), cert. granted on other grounds, 125 S. Ct. 823 (2005). Ranbaxy proffers a similar

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[3] See also Abbott Labs. v. Dey, L.P., 287 F.3d 1097, 1099-1100, 1104-1105 (Fed. Cir. 2002); Laitram Corp. v. Cambridge Wire Cloth Co., 863 F.2d 885, 862 n. 16 (Fed. Cir. 1988)

argument under the doctrine of judicial estoppel, but the Court is not persuaded that the principles of judicial estoppel are applicable in this context. Ranbaxy has offered no case law applying the doctrine of judicial estoppel in the context of claim construction, and in the Court's view, application of judicial estoppel in such a context would essentially undercut the Federal Circuit's clear pronouncements in the Integra line of cases.

In the alternative, even if the Court were to consider the doctrine of judicial estoppel, the Court concludes that Ranbaxy has not demonstrated its applicability. Whether judicial estoppel applies is determined by regional circuit law. In the Third Circuit, the party asserting the doctrine of judicial estoppel must establish that: "(1) the party to be estopped is asserting a position that is irreconcilably inconsistent with one he or she asserted in a prior proceeding; (2) the party changed his or her position in bad faith, i.e. in a culpable manner threatening to the Court's authority or integrity; and (3) the use of judicial estoppel is tailored to address the affront to the Court's authority or integrity." Montrose Med. Group Participating Sav. Plan v. Bulger, 243 F.3d 773, 777-778 (3d Cir. 2001). Ranbaxy contends that Pfizer's position in this case is irreconcilably inconsistent with its position during the prosecution of the '995 patent. Although there may be a degree

of tension between the positions taken by Pfizer in each instance, the Court cannot conclude that those positions are irreconcilably inconsistent. The arguments Pfizer made in the '995 prosecution were directed to the issue of whether the '995 patent claims were anticipated in light of the '893 patent, an analysis which is different from the infringement analysis. Further, the Court is not persuaded that Pfizer's positions demonstrate bad faith or that the use of judicial estoppel is necessary to address an affront to the Court's authority or integrity.

In sum, the Court concludes that its construction of the '893 patent is supported by the specification and the express language of the claims. In contrast, Ranbaxy's proffered construction is primarily based on extrinsic evidence, which is irrelevant to claim construction and inconsistent with the intrinsic evidence of the '893 patent. Accordingly, the Court reads structural formula I of the '893 patent to embrace all trans-form isomers, including enantiomeric atorvastatin calcium.

D. Claim Construction Of The '995 Patent

Pfizer asserts claim 6 of the '995 patent against Ranbaxy's ANDA product. Claim 6 is a dependent claim, which depends on claim 2, which in turn depends on claim 1. Claim 1 is the only independent claim of the '995 patent. The relevant claims provide:

1. [R-(R*,R*)]-2-(4-fluorophenyl)-β, δ-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)-carbonyl]-1H-pyrrole-1-heptanoic acid or (2R-trans)-5-(4-fluorophenyl)-2-(1-methylethyl)-N, 4-diphenyl-1-[2-(tetrahydro-4-hydroxy-6-oxo-2H-pyran-2-yl)ethyl]-1H-pyrrole-3-carboxamide; or pharmaceutically acceptable salts thereof.

2. A compound of claim 1 which is [R-(R*,R*)]-2-(4-fluorophenyl)-β, δ-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)-carbonyl]-1H-pyrrole-1-heptanoic acid.

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6. The hemicalcium salt of the compound of claim 2.

DTX-35, col. 16, l. 60 - col. 17, l. 12 (emphasis added).

The parties' claim construction dispute regarding claim 6 is whether claim 6 can be construed to cover the salt atorvastatin calcium. Ranbaxy contends that claim 6 cannot be construed to cover the salt, because claim 6 depends on claim 2 and claim 2 narrows the subject matter of claim 1 from atorvastatin acid or atorvastatin lactone, or pharmaceutically acceptable salts thereof to the single compound, atorvastatin acid. Ranbaxy argues that because claim 2 does not encompass salts, dependent claim 6 cannot cover the salt atorvastatin calcium. According to Ranbaxy, a reading of claim 6 to include the salt would render the patent invalid under Section 112, paragraph 4.

In response, Pfizer contends that Ranbaxy's claim construction is erroneous, because Ranbaxy incorrectly assumes that claim 6, a dependent claim, must incorporate all of the limitations of claim 2, from which it depends regardless of the

actual language of claim 6. Because claim 6 expressly claims the hemicalcium salt of the compound of claim 2, Pfizer contends that claim 6 is properly construed to encompass the salt atorvastatin calcium.

The Court finds the language of claim 6 to be unambiguous to the extent that claim 6 is meant to claim the salt, atrovastatin calcium. The Court's conclusion is consistent with the express language of the claim and the understanding of the claim language to one skilled in the art. Claim 6 recites "[t]he hemicalcium salt of the compound of claim 2." Claim 2, on which claim 6 depends, defines atorvastatin acid. Thus, claim 6 effectively reads, "[t]he hemicalcium salt of atorvastatin acid." As a matter of standard chemical nomenclature, chemists typically refer to a salt of an acid, even though they are aware that the complete acid is technically no longer present in the salt form. Roush Tr. 910:3-912:4, 914:7-18. The specification of the '995 patent and claim 6 of the '995 patent comport with this standard practice by reciting the full name of the parent acid and then separately identifying the salt-forming ion. DTX-35, col. 4, ll. 3-6; Roush Tr. 914:7-18; Clive Tr. 1510:1-1517:2. Indeed, Ranbaxy utilizes this standard nomenclature in its ANDA application, as well. PTX-1011A at RA011211. Moreover, Ranbaxy's expert, Dr. Clive, had no difficulty understanding the

language of claim 6 as referring to atorvastatin calcium. Clive Tr. 1507:7-1508:2; 1508:14-1509:24.

Despite this standard use of chemical nomenclature and the fact that the meaning of claim 6 is clear to those skilled in the art, Ranbaxy contends that the Court should not interpret claim 6 to refer to atorvastatin calcium, because such an interpretation would render the claim invalid for failure to adhere to the drafting requirements for dependent claims set forth in Section 112. Pursuant to Section 112, paragraph 4, "a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed." Ranbaxy contends that there is a technical problem in the drafting of claim 6, because claim 1, from which claim 6 and claim 2 depend, recites three separate compositions: (1) atorvastatin acid; or (2) atorvastatin lactone; or (3) pharmaceutically acceptable salts of these two compounds. Claim 1 differentiates among these three compositions using the disjunctive "or." As a dependent claim, claim 2 narrows the subject matter of claim 1 from atorvastatin acid; or atorvastin lactone; or pharmaceutically acceptable salts thereof, to the single compound atorvastatin acid. If claim 2 is limited to atorvastatin acid and it excludes the limitation from claim 1 referring to "pharmaceutically acceptable salts thereof," then

Ranbaxy argues that claim 6 cannot be read to encompass that which it expressly names, the hemicalcium salt of atorvastatin.

While the Court recognizes that there may be a technical problem in the drafting of claim 6, the question presented to the Court is whether this drafting problem is sufficient to render the claim invalid if the claim is read consistently with its meaning to those skilled in the art. To reach this conclusion, the Court would be required to declare an issued claim invalid because of the failure to adhere to the drafting technicalities for dependent claims under Section 112, paragraph 4.[4] The Court has been unable to locate any precedent applying Section 112, paragraph 4 to invalidate a patent[5], and based on the legislative

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[4] The Court is not persuaded that claim 6 can be read in any other manner, and Ranbaxy has not offered a plausible alternative reading for claim 6. Because the Court cannot construe the claim in any other manner, the question for the Court is whether claim 6 is invalid. See Phillips v. AWH Corp., 415 F.3d 1303, 1328 (Fed. Cir. 2005) (reaffirming the principle that construing claims so as to maintain their validity is only applicable when the claim language is ambiguous and recognizing that claims cannot be construed differently from their plain meaning to uphold their validity); Nazomi Communications, Inc. v. Arm Holdings, PLC, 403 F.3d 1364, 1368-1371 (Fed. Cir. 2005) (stating that "courts should not rewrite claims to preserve validity"); Rhine v. Casio, Inc., 183 F.3d 1342, 1345 (Fed. Cir. 1999) (recognizing that if "the only claim construction that is consistent with the claim's language and the written description renders the claim invalid," then "the claim is simply invalid").

[5] In arguing that Section 112, paragraph 4 should be considered an invalidating provision, Ranbaxy refers the Court to cases that applied Section 112, paragraph 1 to invalidate a patent for lack of written description and enablement and Section 112, paragraph 2 to invalidate a patent for indefiniteness. Ranbaxy contends that paragraph 4 should not be treated

history of Section 112, paragraph 4, the Court understands the provision to be limited to matters of form, rather than matters of substance. Legislative history concerning this statutory section suggests that its provisions were meant to increase the fees payable to the Patent Office and expedite the prosecution of patent applications to make new technology available to the public more quickly. See S. Rep. No. 89-301 (1965), reprinted in 1965 U.S.C.C.A.N. 2315, 2319-2323. There is no indication in this legislative history that paragraph 4 was intended to be an invalidating provision. The Manual of Patent Examining Procedure ("MPEP") takes an approach consistent with the legislative history by viewing the failure to comply with paragraph 4 as a matter to be addressed through an objection to the claim and not

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differently from paragraphs 1 and 2 of Section 112. The Court understands that the Federal Circuit has applied Section 112, paragraph 1 to invalidate a claim; however, the Court also understands that even this limited use of Section 112, paragraph 1 has not been embraced by all members of the Court. For example, there is significant disagreement over whether "written description" should be divorced from "enablement" and considered a separate and independent ground for invalidity. See e.g. University of Rochester v. G.D. Searle & Co., Inc., 375 F.3d 1303, 1307-1314 (Fed. Cir. 2004) (Rader, J. dissenting and joined by Gajarsa, J. and Linn, J.); Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 976-987 (Fed. Cir. 2002) (Rader, J. dissenting and joined by Gajarsa, J. and Linn, J.). In light of this split among the Circuit judges, the Court is not persuaded that a further extension of invalidity principles to paragraph 4 should be made by this Court.

a rejection of the claim's patentability under 35 U.S.C. § 112, 4.[6] Because the PTO considers improper dependent claims in this manner, the Court is not persuaded that the law of invalidity should be extended to reach Section 112, paragraph 4. Thus, the Court concludes that Section 112, paragraph 4 should not be used to invalidate an issued patent claim.[7] See 35 U.S.C. § 282 (recognizing that issued patent has statutory presumption of validity); Magnivision, Inc. v. Bonneau Co., 115 F.3d 956, 960 (Fed. Cir. 1997) ("Procedural lapses during examination, should they occur, do not provide grounds of invalidity. Absent proof

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[6] MPEP 608.01(n) provides:

> Where a claim in dependent form is not considered to be a proper dependent claim under 37 C.F.R. 1.75(c), the examiner should object to such claim under 37 C.F.R. 1.75(c) and require cancellation of such improper dependent claim or rewriting of such improper dependent claim in independent form. See Ex parte Porter, 25 U.S.P.Q.2d 1144, 1147 (Bd. of Pat. App. & Inter. 1992) (A claim determined to be an improper dependent claim should be treated as a formal matter, in that the claim should be objected to and applicant should be required to cancel the claim (or replace the improper dependent claim with an independent claim) rather than treated by a rejection of the claim under 35 U.S.C. Section 112, fourth paragraph.). The applicant may thereupon amend the claims to place them in proper dependent form, or may redraft them as independent claims, upon payment of any necessary additional fee.

MPEP § 608.01(n) at 600-80 (8th ed. rev. 2, May 2004).

[7] The Court further notes that the PTO raised no objections to the format or dependency of claim 6 or any of the other, similarly-worded claims to atovastatin salts, all of which depend on claim 2. DTX 139 at RA014772-74, RA014784, RA0147804-806, RA014813-14, RA014828-833.

of inequitable conduct, the examiner's or the applicant's absolute compliance with the internal rules of patent examination becomes irrelevant after the patent has issued.").

In sum, the Court interprets claim 6 of the patent to mean the salt of atorvastatin calcium. The Court's claim construction is consistent with the express language of the claim and the understanding of the claim to those skilled in the art. To the extent that the Court's claim construction conflicts with the requirements for dependent claims set forth in Section 112, paragraph 4, the Court concludes that this statutory provision provides no basis to invalidate a claim.

II. Infringement Of The '893 And '995 Patents

A. Applicable Legal Principles

A patent is infringed when a person "without authority makes, uses or sells any patented invention, within the United States during the term of the patent...." 35 U.S.C. § 271(a). A patent owner may prove infringement under either of two theories: literal infringement or the doctrine of equivalents. Literal infringement occurs where each element of at least one claim of the patent is found in the alleged infringer's product. Panduit Corp. v. Dennison Mfg. Co., 836 F.2d 1329, 1330 n. 1 (Fed. Cir. 1987); Robert L. Harmon, Patents and the Federal Circuit 195 & n. 31 (3d ed.1994). In determining whether a patent has been literally infringed, the patent owner has the

burden of proof and must meet its burden by a preponderance of the evidence. SmithKline Diagnostics, Inc. v. Helena Lab. Corp., 859 F.2d 878, 889 (Fed. Cir. 1988) (citations omitted).

Infringement is a two step inquiry. Step one requires a court to construe the disputed terms of the patent at issue. Step two requires a court to compare the accused products with the properly construed claims of the patent. Having resolved the claim construction disputes regarding the '893 and '995 patents, the Court will proceed to a comparison between Ranbaxy's accused ANDA product and the claims of the '893 and '995 patents as construed by the Court.

B. Whether Pfizer Has Established By A Preponderance Of The Evidence That Ranbaxy's ANDA Product Literally Infringes The '893 Patent

The parties have stipulated that Ranbaxy's ANDA product contains the enantiomer atorvastatin calcium. Because the '893 patent has been construed to embrace enantiomers in the trans-form and not just racemates, the Court concludes that Ranbaxy's ANDA product literally infringes claims 1-4 of the '893 patent. The Court also concludes that Ranbaxy is likely to market or sell a composition containing atorvastatin calcium as embraced by claim 8 of the '893 patent, for use in the method claimed by claim 9 of the '893 patent for inhibiting cholesterol biosynthesis in a patient in need of such treatment. Therefore,

the Court concludes that Ranbaxy literally infringes claims 8 and 9 of the '893 patent.

C. Whether Pfizer Has Established By A Preponderance Of The Evidence That Ranbaxy's ANDA Product Literally Infringes The '995 Patent

Ranbaxy has admitted that the active ingredient, atorvastatin calcium, in Ranbaxy's ANDA product is the hemicalcium salt of the R-[R*, R*]-enantiomer. Because Ranbaxy's ANDA and associated Drug Master File ("DMF") indicate that its product will contain atorvastatin calcium, the Court concludes that Ranbaxy literally infringes claim 6 of the '995 patent as that claim has been interpreted by the Court.

III. The Validity Of The '893 Patent Term Extension

A. Applicable Legal Principles

Under the Hatch-Waxman Act, a patentee can obtain an extension of the ordinary patent term if the patent claims an invention which is subject to a regulatory review period before its commercial marketing or use. 35 U.S.C. § 156. Section 156 applies to a "drug product," which is defined, in pertinent part, as "a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Act), . . . including any salt or ester of the active ingredient as a single entity or in combination with another active ingredient." 35 U.S.C. § 156(f)(1), (2).

In applying for a patent extension, the applicant has a duty of candor and good faith toward the PTO, which encompasses a duty to disclose "material information adverse to a determination of entitlement to the extension sought, which has not been previously made of record in the patent term extension proceeding . . . ." 37 C.F.R. § 1.765(a). Information is considered material "where there is a substantial likelihood that the [PTO] . . . would consider it important in determinations to be made in the patent term extension proceeding." Id.

The presumption of validity applies to the PTO's determination to grant a patent term extension. To overcome this presumption, the party challenging the extension must come forward with clear and convincing evidence that the extension is invalid. See Helfix Ltd. v. Blok-Lok Ltd., 208 F.3d 1339, 1346 (Fed. Cir. 2000).

B. Whether Ranbaxy Has Established By Clear And Convincing Evidence That The Patent Term Extension Of The '893 Is Invalid

Ranbaxy contends that the patent term extension of the '893 patent is invalid. Specifically, Ranbaxy contends that (1) the '893 patent does not claim atorvastatin calcium as required by 35 U.S.C. § 156; and (2) Pfizer violated the duty of disclosure by knowingly withholding from the Director representations made by Warner-Lambert regarding the '893 patent during the prosecution of the '995 patent and its European counterparts.

Based on the Court's claim construction of the '893 patent, the Court concludes that Ranbaxy's first argument provides no basis for invalidating the patent term extension of the '893 patent. The Court has construed the '893 patent to embrace atorvastatin calcium, and Pfizer provided the PTO with evidence supporting its assertion that the active pharmaceutical agent in Lipitor® is atorvastatin calcium. The PTO agreed with Pfizer's construction and concluded that the active ingredient in Lipitor® fell within the scope of the '893 patent. The PTO's determination in this regard is entitled to deference. Merck & Co. v. Teva Pharms. U.S.A., Inc., 347 F.2d, 1367, 1373-1374 (Fed. Cir. 2003) (citing Glaxo Ops. UK Ltd. v. Quigg, 894 F.2d 392, 399 (Fed. Cir. 1990)).

Ranbaxy contends that this case is similar to the circumstances in Hoeschst-Roussel Pharmaceuticals, Inc. v. Lehman, 109 F.3d 756 (Fed. Cir. 1997).[8] In the Court's view, however, the circumstances in Hoeschst are distinguishable from the circumstances in this case. In Hoeschst, the Federal Circuit

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[8] Ranbaxy also relies on Hoeschst to argue that the '893 patent does not "claim" atorvastatin calcium, because Ranbaxy contends that the patent lacks a sufficient written description to claim this compound under 35 U.S.C. § 112. Ranbaxy is correct that the Federal Circuit in Hoeschst discussed the meaning of what a patent "claims" by reference to Section 112 for purposes of a patent term extension; however, the Court has previously concluded, in the context of its claim construction analysis, that the '893 patent is not invalid for lack of a written description.

invalidated a patent term extension on the grounds that the patent did not claim the product at issue. The patent in Hoeschst claimed the chemically distinct product 1-hydroxy-tacrine and the method of using that product. The patent did not claim the active ingredient of the product that received FDA approval, i.e. tacrine hydrochloride, or a method of using that ingredient. Rather, the active ingredient of the product at issue metabolized into the patented compound after it was ingested in the body. The Federal Circuit concluded that the active ingredient must be present in the drug product when administered for purposes of obtaining a valid patent term extension. Unlike Hoeschst, in this case, the '893 patent claims the active ingredient in Lipitor®, and therefore, the Court concludes that Hoeschst is inapposite.

Ranbaxy also contends that the patent term extension of the '893 patent is invalid based on Pfizer's alleged failure to disclose material information to the Director. In the context of its claim construction, the Court has concluded that the disclosures made by Warner-Lambert in connection with the prosecution of the '995 patent and foreign counterparts of the '893 patent are irrelevant to a determination of the scope of the claims of the '893 patent. Because this information is not relevant to the patent's scope, the Court concludes that Ranbaxy has not established that the allegedly withheld information is

material such that it was required to be disclosed during the application process for the patent term extension. Accordingly, the Court concludes that Ranbaxy has not established that the patent term extension of the '893 patent is invalid.

IV. The Validity Of The '995 Patent

A. Whether Claim 6 Of The '995 Patent Is Invalid For Non-Statutory Double Patenting Over Pfizer's '080 Patent

1. Applicable Legal Principles

The non-statutory, obvious-type double patenting analysis involves two steps: (1) the court must construe the claim in the earlier patent and the later patent and determine the differences between the two patents, and (2) the court must determine whether the differences in the subject matter between the two claims render the claims patentably distinct. Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 968 (Fed. Cir. 2000). In assessing the differences between the claims, the Court may not treat the earlier claim as prior art. Rather, specific attention must be given to what is claimed in the earlier patent. General Foods Corp. v. Studiengesellschaft Kohle, 972 F.2d 1272, 1278, 1280 (Fed. Cir. 1992) ("[I]t is important to bear in mind that comparison can be made only with what invention is *claimed* in the earlier patent, paying careful attention to the rules of claim interpretation to determine what invention a claim *defines* and not looking to the claim for anything that happens to be mentioned in it as though it were a prior art reference.")

(italics in original). If the later claim is anticipated by or obvious in light of the earlier claim, then the later claim is not patentably distinct from the earlier claim, and it is invalid for obvious-type double patenting. Barr, 251 F.3d at 968.

Non-statutory double patenting is a judicially created doctrine, the purpose of which is to preclude a patent owner "from obtaining an extension of the right to exclude others from practicing his invention through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent." Id. at 967-968; see In re Lonardo, 119 F.3d 960, 965 (Fed. Cir. 1997). Unlike the obviousness inquiry under 35 U.S.C. § 103, non-statutory double patenting does not require an inquiry into the objective criteria of non-obviousness. Geneva Pharms., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1377-1378 n.1 (Fed. Cir. 2003).[9] The party challenging validity on the basis of non-statutory double patenting bears the burden of establishing invalidity by clear and convincing evidence. Symbol Techs., Inc. v. Option, Inc., 935 F.2d 1569, 1580 (Fed. Cir. 1991) (describing burden of proof for non-statutory double patenting as "heavy and unshifting").

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[9] Pfizer contends that, notwithstanding Judge Rader's footnote in Geneva, it is appropriate to consider objective indicia of nonobviousness in the case of nonstatutory, obvious-type double patenting. To the extent such an analysis of these secondary considerations is required, the Court incorporates by reference its discussion of these factors in the obviousness analysis contained in Section IV.B.2 infra.

2. Analysis

In this case, Ranbaxy asserts claims 12 and 14 of United States Patent No. 5,003,080 (the "'080 patent") as the earlier claims to be compared with claim 6 of the '995 patent. The '080 patent expires on March 26, 2008, prior to the expiration date of the '995 patent.

The Court has construed claim 6 of the '995 patent to refer to the specific compound, atorvastatin calcium. As such, claim 6 includes both the chemical structure and the properties of atorvastatin calcium.

Claim 12 of the '080 patent recites:

> A process for the preparation of the compound of Formula Ia [Formula Ia depiction] and the hydroxy acid and pharmaceutically acceptable salts thereof, corresponding to the opened lactone ring of the compound of Formula Ia which comprises:
>
> (a) reacting the compound of Formula XVII [depiction] with a compound of Formula [depiction] wherein R_7 and R_8 are independently hydrogen alkyl of from one to three carbon atoms, phenyl or R_7 and R_8 are taken together as $-(CH_2)_n$ wherein n is 4 or 5 and R_{13} is hydrogen or [depiction] in an inert solvent and treating the resulting intermediate with a 10% aqueas solution of hydrochloric acid to afford the compound of Formula Ia;
>
> (b) and if desired, converting the resulting compound of Formula Ia to a hydroxy acid corresponding to the opened lactone ring of structural Formula Ia by conventional hydrolysis and further, if desired, converting the hydroxy acid to a corresponding pharmaceutically acceptable salt by conventional means, and if so desired, converting the hydroxy acid to a compound of Formula Ia by heating in an inert solvent.

Construing claim 12 in light of the claim language and specification, the Court concludes that claim 12 refers to a process for preparing certain lactone compounds defined by Formula Ia and the opened-lactone ring hydroxy acids and pharmaceutically acceptable salts thereof. DTX-87, col. 56:46-58:24. Step (a) of this process reacts two intermediate compounds under certain identified conditions to provide Formula Ia lactone compounds. Pursuant to step (b), these lactones may then, be converted into a hydroxy acid by opening up the lactone ring. Once converted into a hydroxy acid, the hydroxy acid can then be converted into "pharmaceutically acceptable salts." The hydroxy acid can also be converted back to a lactone compound of Formula Ia, but step (b) does not include the conversion of the pharmaceutically acceptable salts back into the lactone compounds of Formula Ia.

Claim 14 of the '080 patent recites "A process according to claim 12 and for the preparation of (2R-trans)-5-(4-flourophenyl)-2-(1-methylethyl)-N, 4-diphenyl-1-[2-(tetrahydro-4-hydroxy-6-oxo-2H-pyran-2-yl)ethyl]-1H-pyrrole3-carboxamide." Based on the meaning of this express language to one skilled in the art, the Court construes claim 14 as referring to a process to produce the single compound, atorvastatin lactone.

Having construed the claims at issue, the Court must discern the differences among them and determine whether the subject

matter of claim 6 is patentably distinct from the subject matter of claims 12 and 14 of the '080 patent. Claim 14 of the '080 patent claims a process for producing a single compound atorvastatin lactone. Neither this process nor this compound are contemplated by claim 6 of the '995 patent, and Ranbaxy has not demonstrated by clear and convincing evidence that claim 6 of the '995 patent recites an obvious variation of that which is recited in claim 14 of the '080 patent. See Phillips Petroleum Co. v. U.S. Steel Corp., 673 F. Supp. 1278, 1311 (D. Del. 1987) (rejecting claim of double-patenting and concluding that no obvious variation existed where one patent claimed a process and the other claimed a product). The Court is persuaded that the inventions described in claim 14 of the '080 patent and claim 6 of the '995 patent are patentably distinct, and therefore, the Court concludes that claim 6 of the '995 patent is not invalid for non-statutory double patenting in light of claim 14 of the '080 patent.

As for claim 12 of the '080 patent, the Court likewise concludes that claim 12 presents an invention which is patentably distinct from that which is claimed in claim 6 of the '995 patent. Claim 12 of the '080 patent recites a process capable of making a variety of compounds, while claim 6 of the '995 patent is directed to a single compound, atorvastatin calcium. Although the process described in claim 12 can be used to make

atorvastatin calcium if the right starting products are selected, there is nothing in the '080 patent that would lead one to select the chemicals needed to produce the atorvastatin calcium claimed in the '995 patent. Roush Tr. 1902:11-1906:4. The Court is also not persuaded that one skilled in the art would have been led to select the necessary chemicals based on the state of the art at the time. When the '995 patent was filed, the only statin marketed was Lovastatin, which was in the lactone form, not the acid or salt form. In addition, if any salt was preferred at the time, it was the sodium salt form, not the calcium salt form. Roush Tr. 1862:15-1863:3; 1865:17-1866:2; Clive Tr. 1651:18-1655:21. In these circumstances, Ranbaxy has not established that one would be motivated to utilize claim 12 to make atorvastatin calcium, and therefore, the Court is not persuaded that claim 6 of the '995 patent is obvious over the '080 patent for purposes of the double-patenting analysis.

In addition, the Court concludes that claim 12 is appropriately characterized as a genus claim, because claim 12 of the '080 patent can yield a broad variety of compounds. In contrast, claim 6 of the '995 patent is appropriately characterized as a species claim, because it is directed to a single specific compound. Courts have recognized that later species claims are typically not invalidated in light of earlier genus claims on the basis of double patenting. See e.g. In re

Kaplan, 789 F.2d 1574 (Fed. Cir. 1986) (reversing PTO's rejection of claim for double patenting and noting that double patenting does not necessarily arise because a broad or generic claim reads on an invention defined by a narrower more specific claim in another patent); In re Vogel, 422 F.2d 438, 441 (C.C.P.A. 1970) (rejecting double patenting assertion against claims limited to pork based on earlier generic claim to meat).

Further, the invention claimed in the '080 patent has different uses and utilities than that which is claimed in the '995 patent. The utility of claim 12 of the '080 patent is based upon the advantages of the novel synthesis process described in the claim, DTX-87, col. 1, ll. 1-5, 39-50, 66-69, and the process claimed in the '080 patent can be practiced without infringing claim 6 of the '995 patent. In contrast, claim 6 of the '995 patent defines a compound, not a process, and that compound is claimed regardless of the process that is used to create it. See Phillips Petroleum, 673 F. Supp. at 1311. Stated another way, the compound recited in claim 6 does not depend for patentability on the method by which it is made. The compound is not a product-by-process claim, and it can be made without infringing the '080 patent by using a different production method. DTX-35; DTX-139. Indeed, the specification for the '995 patent discloses in its illustrations methods for making the compounds claimed in the patent which are different from the methods disclosed in the

'080 patent. In addition, the utility of the '995 compound is its usefulness as an inhibitor of cholesterol biosynthesis for the treatment of hypercholesterolemia in humans. DTX-35, col. 1, ll. 18-19, 30-32, col. 2, ll. 39-53. The processes claimed in the '080 patent are not sold commercially for these purposes. In these circumstances, the Court cannot conclude that the compound recited in claim 6 of the '995 patent is an obvious variation of the process which is recited in claim 12 of the '080 patent.

Ranbaxy directs the Court to the Federal Circuit's decision in Eli Lilly & Co. v. Barr Laboratories, Inc., 251 F.3d 955 (Fed. Cir. 2001), for the proposition that a later claim to fluoxetine hydrochloride salt was invalid for non-statutory double patenting as anticipated by an earlier claim to pharmaceutically acceptable salts. In the Court's view, however, Ranbaxy misstates the basis for the Barr Court's conclusion of double patenting. In Barr, the Federal Circuit considered claim 1 of the '213 patent, which was directed to a method for treating anxiety in a human by administering an effective amount of fluoxetine or a pharmaceutically acceptable salt thereof. This claim was compared with claim 7 of the '549 patent which claimed a method of blocking the uptake of serotonin by brain neurons in animals by administering the compound fluoxetine hydrochloride. In considering these claims, the Federal Circuit stated that "[a] person of ordinary skill in the art would have recognized that

fluoxetine hydrochloride is a pharmaceutically-acceptable salt of fluoxetine;" however, the claim was not invalid for double patenting on that basis. Rather, the Federal Circuit went on to recognize that the serotonin intake described in claim 7 of the '549 patent is precisely what happens in the treatment of anxiety, and thus, there was no patentable distinction between that which was claimed in claim 1 of the '213 patent and that which was claimed in claim 7 of the '549 patent.[10]

The circumstances in this case differ from the circumstances in Barr, and therefore, the Court is not persuaded that the Barr case dictates the results here. Because the Court has concluded that distinct differences exist between claims 12 and 14 of the '080 patent and claim 6 of the '995 rendering them patentably distinct, the Court concludes that Ranbaxy has not established invalidity of claim 6 of the '995 patent on the grounds of non-statutory double patenting.

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[10] The Federal Circuit also recognized that the earlier claim was directed to a specific species, humans, while the later claim was directed to a genus, animals. The Federal Circuit stated that "[o]ur case law firmly establishes that a later genus claim limitation is anticipated by, and therefore not patentably distinct from, an earlier species claim." Barr, 251 F.3d at 971. As the Court has noted, however, this case presents the converse situation, i.e. a genus claim followed by a species claim, a scenario which does not raise anticipation problems and which is typically permissible. See In re Kaplan, 789 F.2d 1574.

B. Whether Claim 6 Of The '995 Patent Is Obvious In Light Of The '893 Patent

1. Applicable Legal Principles

In pertinent part, 35 U.S.C. § 103 provides that a patent may not be obtained "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious to a person having ordinary skill in the art . . ." 35 U.S.C. § 103. Obviousness is a question of law which is predicated upon several factual inquiries. Richardson-Vicks v. UpJohn Co., 122 F.3d 1476, 1479 (Fed. Cir. 1997). Specifically, in determining whether a patent is invalid as obvious over the prior art, the trier of fact must consider (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed subject matter and the prior art; and (4) secondary considerations of non-obviousness, such as commercial success, long felt but unsolved need, failure of others, and acquiescence of others in the industry that the patent is valid. Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966). The party challenging validity on the grounds of obviousness must establish that the patents are invalid by clear and convincing evidence. C.R. Bard, Inc. v. M3 Sys., 157 F.3d 1340, 1351 (Fed. Cir. 1998).

2. Analysis

Ranbaxy asserts the '893 patent as the relevant prior art to be considered in the analysis of whether the '995 patent is obvious. The '893 patent was cited and relied upon during the prosecution of the '995 patent. DTX 139 at RA014773-774, 779-781, 789-790, 805-806, 813-816, 829-832.

With respect to the level of ordinary skill in the art pertaining to the '995 patent, the parties essentially agree that one skilled in the art would have at least a Bachelor's degree in organic or medicinal chemistry, a general knowledge of statins, several years of bench work in organic molecule synthesis and some general knowledge of biochemistry and enzymology. The parties also agree that one skilled in the art would have knowledge pertaining to the stereochemistry of pharmaceutically active ingredients and the resolving of racemates. Roush Tr. 1773:22-1774:14; 1786:12-1788:4; Scallen Tr. 1112:10-14. Ranbaxy asserted at trial that one skilled in the art would have a Ph.D., but Ranbaxy contends that this educational difference is immaterial to the obviousness analysis. To the extent the Court is required to make a finding on this disputed issue, the Court finds that one skilled in the art is not necessarily required to have a Ph.D. in light of the skill and knowledge base one can obtain through the work experience identified by the parties as essential to the level of ordinary skill in the relevant art.

Having identified the level of skill in the art and the relevant prior art, the Court must next consider the differences between the prior art and the claimed subject matter, as well as the objective indicia of non-obviousness. In conducting this analysis, the Court also considers whether one skilled in the art would have been motivated to modify the '893 patent to reconstruct atorvastatin calcium.

Unlike the '995 patent which is specifically directed to the calcium salt of atorvastatin, the '893 patent does not specifically name, exemplify or depict a specific calcium salt. Rather, the '893 patent broadly includes calcium among at least 50 possible salts, and mentions no preference for calcium as compared with the other possible salts. DTX 13, col. 7, ll. 1-17; Clive Tr. 1581:6-1583:17; Roush Tr. 1860:1-1862:14. Indeed, if any salt was preferred at the time among the more than fifty to one hundred available, the evidence indicates that it would have been sodium salt. Clive Tr. 1651:18-1655:6; Roush Tr. 1862:15-1865:16; PTX 2058, col. 5, first paragraph. Further, the art at the time suggests that the selection of salts is a difficult task. Given the unique properties each salt imparts to the parent compound, salt selection is not a routine process and the success of a given salt is not easily predicted. DTX-3081; Roush Tr. 1865:17-1871:16; Clive Tr. 1524:1-1536:10. In these circumstances, the Court finds that, at best, it would have been

obvious for medicinal chemists to try various salts in an attempt to find a salt with properties suitable for pharmaceutical use. However, "obvious to try" does not equate with obviousness for purposes of Section 103. See e.g. In re Deuel, 51 F.3d 1552, 1559 (Fed. Cir. 1995) ("'Obvious to try' has long been held not to constitute obviousness."). Accordingly, the Court is not persuaded that one skilled in the art would have been motivated to select calcium, or that one could have a reasonable expectation that the selection of calcium would be successful.

Ranbaxy also contends that it would have been obvious to one skilled in the art to obtain atorvastatin calcium from the racemates of atorvastatin disclosed in the '893 patent. The Court disagrees with Ranbaxy's position. Although the '893 patent identifies racemic atorvastatin lactone as compound 1, there is nothing in the '893 patent expressing a preference for that compound as opposed to the thousands of other individual compounds identified by the '893 patent. Moreover, the Court is not persuaded that one skilled in the art during the relevant time period would have selected compound 1 as a starting point for the ultimate separation of that compound into its individual enantiomers. First, the prior art indicates that the motivation at the time was to develop racemates and make structural changes to the compounds to increase their activity, not to resolve those racemates into individual isomers. The resolution of racemates

into their individual isomers yielded, at best, an expectation of a two-fold increase in activity. This modest increase in activity was offset by the difficulty and complexity of the resolution process, as well as the reduced yield and increased waste disposal problems. Roush Tr. 1807:15-1813:20, 1820:16-1830:4, 1831:14-1837:3; PTX 2058, 2064, 2681, 2694. Further, the Court is persuaded by Dr. Roush's testimony, that if there was a motivation to resolve the racemates, a medicinal chemist attempting to improve the activity of the compounds in the '893 patent would begin with the most active compound identified in the patent, compound 3. As Dr. Roush explained, expectations at the time would have led a medicinal chemist to expect no more than a two-fold increase in activity from racemic compound 1, which is the same activity level as compound 3 before compound 3 was separated into its component enantiomers. Roush Tr. 1838:18-1845:5, 1846:8-1847:14, 1853:13-1854:15, 2018:6-2022:4. As a result, the Court cannot conclude that there was any motivation in the prior art or reasonable expectation of success that would lead one skilled in the art to resolve compound 1 into its individual enantiomers.

In addition to the differences between the prior art and claim 6 of the '995 patent and the lack of motivation to resolve compound 1 described in the '893 patent into its individual enantiomers, the Court also concludes that objective indicia of

non-obviousness support the validity of claim 6 of the '995 patent. Prior to the filing date of the '995 patent, no commercial statin had been marketed in the form of a calcium salt. Roush Tr. 1871:6-11. Lipitor®, which contains as its active pharmaceutical agent the compound recited in claim 6 of the '995 patent, was the first such product and its commercial and medical success, though unexpected, has been well-documented. Susserman Tr. 810:2-814:20; Bokhart Tr. 2350:13-19, 2374:4-2375:19. Ranbaxy contends that Lipitor®'s success is the result of Pfizer's marketing strategies and not the efficacy of the product; however, Pfizer has produced several studies and clinical trials which demonstrate the benefits derived from the use of atorvastatin calcium and its superiority over other compounds. See e.g. PTX-337, 336, 351, 354, 347, 366, 2007; Jones Tr. 1711:24-1717:27; Sasiela Tr. 2450:14-2451:9, 2460:1-2462:4. In the Court's view, this evidence is sufficient to demonstrate that Lipitor®'s success was the result of its medical efficacy compared with other products.

To this effect, the Court also finds that Lipitor® satisfied a long-felt need in the medical community to provide patients with more effective statins to help them achieve their LDL goals. Sasiela Tr. 2417:20-2419:3; Susserman Tr. 795:2-20; Bowman Tr. 2578:4-2581:10; Jones Tr. 1696:6-1699:16; PTX 349. Despite the efforts of others to make effective statins, Lipitor® proved to

be more successful than those products available on the market at the time. Indeed, the fact that Ranbaxy has chosen to copy Lipitor® in its ANDA further demonstrates the success and efficacy of Lipitor® compared with other available products.

In sum, the Court concludes that Ranbaxy has not demonstrated that claim 6 of the '995 patent is obvious in light of the '893 patent. The '893 patent claims a genus of compounds, while the '995 patent claims a species of that genus. There was no motivation in the prior art to select the species compound of atorvastatin calcium from the genus of compounds identified in the '893 patent, and absent such a motivation, the Court cannot conclude that the '893 genus patent renders the '995 species patent obvious. In addition, the Court concludes that indicia of non-obviousness support the validity of the '995 patent. Accordingly, the Court concludes that Ranbaxy has not demonstrated by clear and convincing evidence that claim 6 of the '995 patent is obvious.

C. Whether Claim 6 Of The '995 Patent Is Anticipated By The '893 Patent

1. Applicable Legal Principles

The party challenging validity on the basis of anticipation under 35 U.S.C. § 102(g), must show that the potentially invalidating patent or invention (1) qualifies as prior art; (2) was not abandoned, suppressed or concealed; and (3) is identical

to the claimed invention or process. To show identicality between prior art and the claimed invention, the party challenging validity must show that each and every step or element of the claimed process or invention is disclosed in a single prior art reference or embodied in a single prior art device or practice, either expressly or inherently. Hazani v. United States Int'l Trade Comm'n, 125 F.3d 1473, 1477 (Fed. Cir. 1997). "[I]nvalidity by anticipation requires that the four corners of a single, prior art document describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation." Advanced Display Sys., Inc. v. Kent State Univ., 212 F.3d 1272, 1282 (Fed. Cir. 2000).

2. Analysis

Ranbaxy contends that claim 6 of the '995 patent is anticipated by the '893 patent. Specifically, Ranbaxy contends that the '893 patent discloses atorvastatin lactone and the hydroxy acid and pharmaceutically acceptable salts derived from the lactone. Ranbaxy also points out that the '893 patent discloses calcium as one of the seven listed pharmaceutically acceptable salts.

In response, Pfizer contends that the prior art disclosure of a racemate does not anticipate either of its individual isomers. Pfizer also contends that the earlier disclosure of a

genus does not anticipate an undisclosed species member of the genus.

The Federal Circuit has recognized that the "earlier disclosure of a genus does not necessarily prevent patenting a species member of that genus." Eli Lilly & Co. v. Bd. of Regents of the Univ. of Washington, 334 F.3d 1264, 1270 (citing Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1380 (Fed. Cir. 2001)). Although the '893 patent mentions calcium as one of the seven listed pharmaceutically acceptable salts, the '893 patent does not expressly identify atorvastatin calcium, the species compound claimed in the '995 patent. In the Court's view, an approach to the '893 patent which interprets this passing reference to calcium as an anticipation of the later claimed compound atorvastatin calcium is the type of "mechanistic dissection and recombination" that results in a finding of anticipation by hindsight. See In re Ruschig, 343 F.2d 965, 974 (C.C.P.A. 1965) (disavowing "the mechanistic dissection and recombination of the components of the specific illustrative compounds in every chemical reference containing them, to create hindsight anticipations with the guidance of an applicant's disclosures, on the theory that such reconstructed disclosures describe specific compounds within the meaning of section 102"). Further, courts considering issues related to racemates and their individual isomers have concluded that a prior art disclosure of

a racemate does not anticipate the individual isomers of the racemate or render the individual isomers of the racemate obvious. See In re May, 574 F.2d 1082 (C.C.P.A. 1978) (holding that "the novelty of an optical isomer is not negated by the prior art disclosure of its racemate"); Ortho-McNeil Pharms, Inc. v. Mylan Labs., Inc., 348 F. Supp. 2d 713, 720-721, 761-764 (N.D.W. Va. 2004) (discussing patentability of an optically active isomer (enantiomer) over prior art and use in commerce of its racemic mixture); see also Eli Lilly v. Generix Drug Sales, Inc., 460 F.2d 1096, 1104 (5th Cir. 1972) (noting that individual d-isomer was the "repository of the useful and novel invention claimed" and affirming infringement of claim limited in words to a racemic mixture). Accordingly, the Court concludes that Ranbaxy has not established that the species compound claimed in the '995 patent is anticipated by the genus of compounds claimed in the '893 patent.

V. The Enforceability Of The '995 Patent Due To Inequitable Conduct

A. Applicable Legal Principles

Patent applicants and their patent attorneys have a duty of candor, good faith and honesty in their dealings with the PTO. 37 C.F.R. § 1.56(a). The duty of candor, good faith and honesty includes the duty to submit truthful information and the duty to disclose to the PTO information known to the patent applicants or

their attorneys which is material to the examination of the patent application. Elk Corp. of Dallas v. GAF Bldg. Materials Corp., 168 F.3d 28, 30 (Fed. Cir. 1999). Breach of the duty of candor, good faith and honesty may constitute inequitable conduct. Id. If it is established that a patent applicant engaged in inequitable conduct before the PTO, the entire patent application so procured is rendered unenforceable. Kingsdown Med. Consultants v. Hollister Inc., 863 F.2d 867, 877 (Fed. Cir. 1988).

To establish inequitable conduct due to the failure to disclose material information or the submission of false information, the party raising the issue must prove by clear and convincing evidence that (1) the information is material; (2) the knowledge of this information and its materiality is chargeable to the patent applicant; and (3) the applicant's submission of false information or its failure to disclose this information resulted from an intent to mislead the PTO. Id. Information is deemed material if there is a substantial likelihood that a reasonable examiner would have considered the material important in deciding whether to issue the application as a patent. See Elk Corp., 168 F.3d at 31; Mobil Oil Corp. v. Advanced Envtl. Recycling Techs., Inc., 869 F. Supp. 251, 254 (D. Del. 1994). Accordingly, a reference does not have to be prior art to be material information that must be disclosed to the PTO. See 37

C.F.R. § 1.56; Mobil Oil Corp., 869 F. Supp. at 255. Further, "an otherwise material reference need not be disclosed if it is merely cumulative of or less material than other references already disclosed." Elk Corp., 168 F.3d at 31.

Intent to deceive is rarely established by direct evidence, and therefore, may be inferred from the facts and circumstances surrounding the applicant's overall conduct. See Molins PLC v. Textron, Inc., 48 F.3d 1172, 1180 (Fed. Cir. 1995). In determining whether the applicant's overall conduct evidences an intent to deceive the PTO, the Federal Circuit has emphasized that the challenged "conduct must be sufficient to require a finding of deceitful intent in the light of all the circumstances." Kingsdown Med. Consultants, 863 F.2d at 873. Once materiality and intent have been established, the court must conduct a balancing test to determine "whether the scales tilt to a conclusion that 'inequitable conduct' occurred." Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1256 (Fed. Cir. 1997). Generally, the more material the omission, the less the degree of intent that must be shown to reach a conclusion of inequitable conduct. Elk Corp., 168 F.3d at 32.

The question of whether inequitable conduct occurred is equitable in nature. As such, the ultimate question of whether inequitable conduct occurred is committed to the sound discretion

of the trial court. Elk Corp., 168 F.3d at 30-31; Kingsdown Med. Consultants, 863 F.2d at 876.

B. Whether Warner-Lambert Engaged In Equitable Conduct During The Prosecution Of The '995 Patent

Ranbaxy contends that, during the prosecution of the '995 patent, Warner-Lambert withheld material information concerning other patents in their portfolio and misrepresented the cholesterol inhibition activity of the compounds at issue. Specifically, Ranbaxy contends that the '080 patent filed in February 1988 and its CIP application filed in February 1989 were not disclosed to the PTO, but both of these references give rise to prima facie unpatentability of the '995 patent based on obvious-type double patenting. Ranbaxy also contends that Warner-Lambert withheld results from in vivo experiments called AICS screens ("AICS data") and results from in vitro experiments called CSI screens ("CSI data") which demonstrated no significant difference in activity of the material compounds. Ranbaxy contends that this information was contrary to the representations made by Warner-Lambert, through Dr. Roth and Dr. Daignault, that its compound had "activity at least ten-fold more than that of the racemate," and therefore, showed "surprising and unexpected results" because the activity of the R isomer would only be expected to be twice that of the racemic mixture. As a result of the failure to disclose this information, Ranbaxy

contends that Warner-Lambert intentionally deceived the PTO as to the patentability of the '995 invention.

In response, Pfizer contends that Ranbaxy cannot establish intent to deceive the PTO. Pfizer contends that Dr. Roth dealt with two separate attorneys for the '080 patent and the '995 patent, and that he never considered whether the '080 patent should have been brought to the attention of the '995 patent examiner, because the patents involved what Dr. Roth considered to be two very different inventions. Pfizer also contends that Dr. Daignault had limited involvement in the '995 patent prosecution and that while he signed papers for the '080 patent, he did not do significant substantive work on it. As a result, Pfizer contends that Dr. Daignault was not knowledgeable in the '080 patent, and therefore, he had no deliberate intent to withhold it from the PTO.

As for the AICS and CSI data, Pfizer contends that Ranbaxy's allegations of inequitable conduct based on the alleged withholding of data are hindsight reconstructions that fail to take into account the "real world" conditions under which Dr. Roth discovered Lipitor®. Pfizer contends that Dr. Roth had no intent to deceive the PTO and that the data identified by Ranbaxy is not material.

1. The '080 patent and the CIP application for the '080 patent

Reviewing the record as it relates to the '080 patent and the CIP application for the '080 patent, the Court concludes that Ranbaxy has not established that Dr. Daignault or Dr. Roth intentionally deceived the PTO by failing to disclose these references. Although Dr. Daignault signed the application papers for the '080 patent as the attorney of record, Dr. Tinney was responsible for the substantive preparation of the application. DTX-88 at RA014464-465; Daignault Tr. 1267:20-1269:6; Tinney Tr. 2225:18-2227:5. At the time, Dr. Tinney could not sign the papers, because he had not yet passed the patent bar. Prosecution of the '080 patent was abandoned in favor of the expanded CIP application. The expanded CIP application, and not the original '080 application contains the express disclosure of enantiomers upon which Ranbaxy relies.

By the time the '080 CIP application was ready for filing, Dr. Tinney had his PTO registration. As a result, Dr. Tinney, prepared and prosecuted the '080 CIP application. Dr. Daignault had no involvement in the CIP, and Dr. Tinney and Dr. Daignault both testified that they did not discuss the '080 CIP application with each other. Daignault Tr. 1269:22-1271:4, 1271:12-1272:14; Tinney Tr. 2237:16-2239:9; 2231:6-17.

The '995 patent application was prepared and prosecuted by a different Warner-Lambert attorney, Joan Theirstein. Dr. Tinney had no involvement in the '995 prosecution, and Dr. Tinney and Ms. Theirstein never discussed the '080 issued patent or CIP application with each other. DTX-139; Tinney Tr. 2240:1-24; Theirstein Dep. Tr. 91:14-92:22. In December 1991, Ms. Theirstein left Warner-Lambert suddenly and Dr. Daignault was required to assume the prosecution of the '995 patent on short notice. Daignault Tr. 1260:10-1262:12, 1263:4-24; Theirstein Dep. Tr. 110:13-15. Dr. Daignault filed and argued the appeal of the anticipation rejection to the PTO Board of Appeals and signed the issue fee transmittal to the PTO in early September 1993. Daignault Tr. 1263:14-20; 1264:3-5; 1265:6-17; 1266:16-1267:19; 1273:11-1274:11; DTX 139 at RA014808-809. Dr. Daignault testified that he was not consciously aware of the '080 CIP application at the time he prosecuted the '995 appeal in December 1991, which was approximately two years after his involvement with the '080 patent. Daignault Tr. 1271:12-1272:5; 1274:12-1275:10; 1314:24-1315:24. Dr. Daignault also testified that he never considered citing the '080 patent during the '995 appeal period or thereafter. Dr. Daignault was responsible for more than 150 ongoing active patent prosecutions in addition to his administrative duties at the time. Daignault Tr. 1272:6-14. Dr. Daignault's involvement with the '080 patent and the CIP

application were limited and the duties he assumed with regard to the '995 patent were likewise limited in nature. In these circumstances, the Court cannot conclude that Dr. Daignault's failure to consciously consider the '080 patent or the CIP was the result of any intent to deceive the PTO.

With respect to Dr. Roth, the evidence adduced at trial demonstrates that Dr. Roth dealt with two separate attorneys during the '080 and '995 patent prosecutions. Roth Tr. 305:10-24. Dr. Roth testified that he never considered whether the '080 patent or CIP application should have been brought to the attention of the patent examiner. Roth Tr. 306:1-12. In this regard, Dr. Roth testified that he considered the patents to involve two different processes. Roth Tr. 305:1-12, 306:1-12. In these circumstances, the Court cannot conclude that Dr. Roth's views were based on any intent to deceive the PTO. Accordingly, the Court is not persuaded that Dr. Roth acted intentionally to withhold the '080 patent from the PTO.

2. The AICS data

Ranbaxy contends that Dr. Roth intentionally withheld in vivo rat data generated in an AICS screen from the PTO during the prosecution of the '995 patent. This data was contained in a May 1989 research report in which the author, a biologist named Dr. Krause, concluded that the R-isomer was "approximately twofold more active at inhibiting cholesterol synthesis acutely in vivo"

compared to racemic atorvastatin. DTX-11. Ranbaxy contends that this material was intentionally withheld from the PTO, because it contradicted other data provided by Warner-Lambert to support its assertion that the R-isomer was ten times more active than the racemate.

Reviewing the testimony and evidence adduced at trial in light of the applicable legal standards, the Court concludes that Ranbaxy has not demonstrated by clear and convincing evidence that the in vivo rat data was material or intentionally withheld by Dr. Roth. AICS in vivo assays are not used to measure the absolute or intrinsic inhibitory activity of a compound. Particularly, the fact that these assays are conducted in vivo, in a live animal, presents a variety of complicating factors that make these studies unreliable for determining whether a given compound is having a direct effect on the inhibition of cholesterol synthesis. Roth Tr. 169:5-8, 170:17-171:6; 293:13-295:1. Instead, in vitro data is the best and most relevant data for comparing the absolute or intrinsic activity of compounds to inhibit cholesterol biosynthesis. Roth Tr. 178:13-187:6, 261:20-263:5. Accordingly, the Court cannot conclude that Ranbaxy has established, by clear and convincing evidence, that this data was material.

In addition, the Court cannot conclude that Dr. Roth intentionally withheld this data from the PTO with the intent to

deceive. Dr. Roth testified that he believed in vivo data could not be used to measure the intrinsic inhibitory activity of a compound, because it was influenced by a number of factors such as metabolism and absorption in the body. Roth Tr. 293:13-295:1. Indeed, Dr. Roth did not use AICS data to make quantitative comparisons of the activity of compounds or in developing his SAR or QSAR theories which led to the discovery of atorvastatin calcium. Roth Tr. 292:20-294:7. Thus, the Court finds that the evidence demonstrates that Dr. Roth made a good faith determination that the AICS data was not relevant.[11] Roth Tr. 291:19-294:7, 343:1-344:6, 364:11-19.

Ranbaxy argues that the AICS data was submitted to the FDA when Warner-Lambert sought approval for Lipitor®, and therefore, it must have been material data. However, a determination of materiality before the PTO is not governed by that which is required for submission to the FDA. See Ortho-McNeil Pharm., 2004 WL 2973831 at *23-24. Ranbaxy refers the Court to the Federal Circuit's decision in Bruno Independent Living Aids, Inc. v. Acorn Mobility Services, Ltd., 394 F.3d 1348 (Fed. Cir. 2005)

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[11] See e.g. Hoffmann-LaRoche, Inc. v. Promega Corp., 323 F.3d 1354, 1361 (Fed. Cir. 2003) (reversing finding of intent to deceive where evidence showed that inventors, in good faith, did not believe results of experiment were relevant); Allied Colloids Inc. v. American Cyanamid Co., 64 F.3d 1570, 1578 (Fed. Cir. 1995) ("It is not inequitable conduct to omit telling the patent examiner information that the applicant in good faith believes is not material to patentability.").

to support its argument that material submitted to the FDA should have been disclosed to the PTO and the failure to do so demonstrates an intent to deceive. In the Court's view, however, the Bruno case is distinguishable from the circumstances here. In Bruno, the Federal Circuit rejected the patentee's assertion that certain representations made to the FDA about prior art were only relevant to securing FDA approval and had no bearing on whether the patentee knew those references were material prior art for purposes of patentability. In reaching this conclusion, the Federal Circuit highlighted the fact that the FDA submission was prepared by the same individual who was involved in the prosecution of the patent-in-suit and that individual had asked an attorney to conduct a prior art search in preparation for the filing of the patent application. Id. at 1352. Unlike Bruno, the FDA submission in this case does not involve prior art but the submission of data, which the Court has already concluded was withheld based on the credible assertion that the data was unreliable. Further, Dr. Roth was not involved in the FDA submissions, and therefore, the FDA submissions cannot be used to infer that Dr. Roth believed the AICS data was material to patentability. Roth Tr. 332:23-24. Accordingly, the Court cannot conclude that Ranbaxy has established by clear and convincing evidence that Dr. Roth intentionally withheld material

data from the PTO with the intent to deceive the PTO as to the inhibitory activity of atorvastatin calcium.

3. The CSI data

Ranbaxy also contends that Warner-Lambert intentionally withheld certain CSI data and manipulated the CSI data that was disclosed to deceive the PTO and support its assertions concerning the activity of atorvastatin calcium. Ranbaxy contends that like the AICS data discussed above, the withheld CSI data showed the comparative activity between the R-isomer and the racemic compound to be far lower than the "ten times" difference asserted by Warner-Lambert. Ranbaxy contends that this data was material to patentability and not cumulative, and therefore, Warner-Lambert had a duty to disclose it.

The biological data contained in the '995 patent specification were generated from an in vitro assay called CSI. The CSI assay measures the absolute or inherent activity of compounds to inhibit cholesterol biosynthesis. The data for the sodium salt of the R-isomer and S-isomer are from the same experiment, CSI test 120, the most recent CSI experiment available to Dr. Roth at the time. The data collected for racemic atorvastatin sodium salt represents an average of five separate assays.

Ranbaxy contends that the use of this average number was misleading and demonstrates an intent to deceive the PTO. The Court concludes there was no intent to deceive. The experts agree that head-to-head testing provides the best way to compare quantitative differences in activity. Roth Tr. 264:22-265:18; Scallen Tr. 1133:3-6. Dr. Roth initially located a head-to-head comparison for the sodium salts of the R-isomer and S-isomer, but the sodium racemate was not included in that experiment. Dr. Roth did what he considered to be the next best thing, which was to collect all of the then-available data for the racemate and calculate the historical average. Roth Tr. 264:22-272:16; PTX 2538 at P0236600. When asked to check for additional data, Dr. Roth then found a single head-to-head comparison with all three forms of calcium salt in CSI-118. Roth Tr. 265:21-267:9, 273:1-276:5. This data was submitted to the PTO in Dr Roth's declaration. Roth Tr. 273:5-275:19, 279:11-15; PTX 2538 at P0236601-602; PTX 2055.

Ranbaxy also points to other data which Dr. Roth allegedly concealed, including the atorvastatin lactone value from CSI-107, the racemic sodium salt value from CSI 118 and the racemic calcium salt data from CSI 119. The Court finds that this evidence is insufficient to establish clearly and convincingly that this data was withheld to intentionally deceive the PTO. Dr. Roth has alleged credible and good faith reasons for his

failure to include certain data in his reports. For example, the atorvastatin compounds tested in CSI-107 were based on Warner-Lambert's first crude attempt to resolve racemic atorvastatin. Roth Tr. 252:3-253:5; PTX 283 at P0250205. The results were impure R-trans and S-trans isomers that were contaminated with their opposite isomer. Dr. Roth did not know what effect this contamination would have on the biological activity of the R-isomer, so he relied on comparisons using pure isomers. Roth Tr. 265:19-266:11, 397:18-398:22; DTX 3323.

As for Ranbaxy's assertion that the racemic sodium value from CSI-118 should have been disclosed along with the calcium values, Dr. Roth explained that it is inappropriate to compare across salts, because different salts have different solubilities. Thus, Dr. Roth believed that it was only appropriate to compare the same salts within an experiment. Roth Tr. 263:16-265:18, 414:24-415:21, 419:5-420:5. Along a similar vein, Dr. Roth did not provide the data from CSI-119, because he believed it was inappropriate to compare individual data points from different experiments. CSI 119 was not a head-to-head comparison, and was not a repeat of CSI 118. Moreover, the CSI 119 experiment showed a worse than normal solubility problem noted as "chunks," a problem which was not noted in the CSI 118

experiment[12], which was fully disclosed in Dr. Roth's declaration and is the only CSI experiment where all three calcium salts of racemic atorvastatin and the R-isomer and the S-isomer were tested head-to-head. In the Court's view, sound reasons support Dr. Roth's decision not to submit certain CSI data to the PTO, and therefore, the Court cannot conclude that Ranbaxy has demonstrated that Dr. Roth intended to deceive the PTO by withholding certain CSI data.

4. Summary

In sum, the Court concludes that Ranbaxy has not established by clear and convincing evidence that the '995 patent was procured through inequitable conduct. Although the '080 patent was not revealed during the prosecution of the '995 patent, the Court is not persuaded that it was intentionally withheld. The circumstances related to the drafting and prosecution of the '080 and '995 patents, including the workload of Dr. Daignault and his limited roles in each of the patents, suggest that Dr. Daignault was not dishonest in his claim that he did not consider the '080 patent during the prosecution of the '995 patent. Similarly, the

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[12] The technician noted that the calcium salt compounds in CSI 118 were "insoluble," but there was no notation regarding chunks. As Dr. Dietschy explained the statins as a whole have poor solubility, but solutions with "gross lumps" are the worse scenario and are "unacceptable . . . to begin with." Dietschy Tr. 2116:6-2117:17, 2124:4-2129:11, 2205:24-2207:19; PTX 2115-2118.

Court cannot conclude that Dr. Roth was dishonest in his view that the '080 patent and '995 patents referred to two separate inventions.

As for the data submission issue, the Court is not persuaded that Warner-Lambert manipulated or "cherry picked" data with deceitful motives to achieve a deceitful result. Pfizer had ample data to support the claims it made to the PTO, and it provided the PTO with the data it believed was scientifically sound. The Court is not persuaded that the instances of non-disclosure cited by Ranbaxy are sufficient to demonstrate an intent to deceive the PTO. Pfizer has advanced reasonable and credible grounds for the non-production of certain data that weigh against a conclusion that Warner-Lambert scientists and employees were intentionally deceiving the PTO. Because Ranbaxy has not met its burden of establishing inequitable conduct, the Court will enter judgment in favor of Pfizer and against Ranbaxy on Ranbaxy's counterclaim that the '995 patent is unenforceable as a result of inequitable conduct.

CONCLUSION

For the reasons discussed, the Court concludes that Pfizer has established that Ranbaxy's ANDA product literally infringes the '893 and '995 patents, and therefore, the Court will enter judgment in favor of Pfizer and against Ranbaxy on Pfizer's claims of infringement. In addition, the Court concludes that

Ranbaxy has not established that the '893 patent is invalid under 35 U.S.C. § 112, ¶ 1, or that the patent term extension of the '893 patent is invalid, and therefore, the Court will enter judgment in favor of Pfizer and against Ranbaxy on Ranbaxy's counterclaims of invalidity of the '893 patent and invalidity of the patent term extension. With respect to the '995 patent, the Court further concludes that Ranbaxy has not established unenforceability as a result of inequitable conduct or invalidity based on double patenting, obviousness and anticipation, and therefore, the Court will enter judgment in favor of Pfizer and against Ranbaxy on Ranbaxy's counter claims of invalidity and unenforceability of the '995 patent.

Pfizer shall submit, with notice to Ranbaxy, a proposed Final Judgment Order by December 23, 2005.